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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 33

Application Number	10/716,360
Filing Date	11/18/2003
First Named Inventor	Thomas
Art Unit	3772
Examiner Name	Nihir B. Patel
Attorney Docket Number	1440.2032-001 / CMD-069

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
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- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Cleveland Medical Devices Inc.		
Signature			
Printed name	Brian M. Kolkowski		
Date	3/12/2009	Reg. No.	36,847

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Thomas	
Serial No.:	10/716,360	Art Unit: 3772
Filed:	November 18, 2003	Attorney docket No. 1440.2032-001
For:	Gas system and methods for enabling respiratory stability	Attorney docket No. CMD-069
Examiner:	Nihir B. Patel	

March 12, 2009

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MATTHEW BEUTLER — Typed or printed name of certifier

APPEAL BRIEF TRANSMITTAL

Dear Sir:

Appellants' herein submit their brief as required under 37 C.F.R. §41.37. The Commissioner is hereby authorized to charge the $255 dollar fee for the Appeal Brief to Deposit Account 502704. The Appellants herein certify that they are a small entity. The Commissioner is further authorized to charge any deficiency or to credit any overpayment to Deposit Account 502704.

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The Appellants' believe this Appeal Brief complies fully complies with 37 C.F.R. §41.37.

Respectfully submitted,

3/12/2009
Dated

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Application of Thomas et. al	
Serial No.:	10/716,360	Art Unit: 3772
Filed:	November 18, 2003	Attorney Docket No. 1440.2032-001
For:	Gas system and methods for enabling respiratory stability	Attorney Docket No. CMD-069
Examiner:	Nihir B. Patel	

March 12, 2009

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Dear Sir:

This Brief supports the appeal to the Board of Patent Appeals and Interferences from the final Office Action with mail date October 16, 2008, in the application listed above. Appellant filed a timely response to the rejection and a timely notice of appeal on January 16, 2009. The Appellant herein asserts that Beth Israel Deaconess Medical Center is a non-profit organization and is therefore entitled to small entity status.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Beth Israel Deaconess Medical Center, 330 Brookline Avenue, FN-214-1, Boston, MA 02215. Cleveland Medical Devices Inc., also a small entity, who is assisting in this appeal, has an option to license this technology from Beth Israel at some point in the future.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-13 are the subject of this Appeal. Claims 1-13 stand rejected. Claims 14-68 have been withdrawn from consideration.

IV. STATUS OF AMENDMENTS

An amendment after final rejection was filed January 16, 2009. Included in the amendment after final were amendments to claims 1-3, 5, 8-9 and 12-13. However, these amendments were not entered for purposes of this appeal because it was asserted by the Examiner that the proposed amendments to claims 1-3 and claim 8 raised new issues that would require further consideration and/or search.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention relates to a method and device for treatment of sleep disordered breathing. More particularly, the claimed invention relates to a method and

device to treat sleep disordered breathing through the use of substantially low concentrations of carbon dioxide mixed with pressurized air and delivered to a target for inhalation using a patient centric ventilatory space module such as a face mask or a nasal canula. (*see page 3, lines 12-21 and page 5, lines 27-29*).

Claim 1 is directed to an embodiment of the present invention related to a device for stabilizing breathing. The device of Claim 1 comprises a source of carbon dioxide (*see page 12, lines 9-11; page 9, line 25-page 10 line 5*), an assembly for combining pressurized air with substantially low concentrations of the carbon dioxide (*see page 6, lines 12-30; page 13, line 19-page 16 line 24*), and a patient centric ventilatory space module (PCVSM) coupled to the assembly providing the resulting gas mix for inhalation by a given target (*see page 5, lines 27-29; page 9, lines 4-6*).

With respect to the source of carbon dioxide included in Claim 1, this source includes but is not limited to a pressurized source or can be a patient's own exhaled carbon dioxide (*see page 12, lines 9-11; page 9, line 25-page 10 line 5*).

With respect to the assembly included in Claim 1, the assembly provides a mixing chamber for air and substantially low concentrations of carbon dioxide, allowing air to be mixed before inhalation by a target (*see page 13, line 19-page 14, line 9*). The assembly also includes but is not limited to many other components to control mixing of air and carbon dioxide, including but not limited to various types of valves, gas sensors, manometers and the like (*see page 13, line 19-page 16 line 24*).

With respect to the PCVSM included in Claim 1, the PCVSM can take many forms including but not limited to an incubator, a sealed or unsealed mask, a tent, or nasal canula (*see page 5, lines 27-29; page 9, lines 4-6*). Further, the PCVSM can also include

but is not limited to sensors of various types such as a Nihon Kohden sensor (*see page 5, lines 23-25; page 6, lines 17-19*).

Claim 8 is directed to an embodiment of the present invention related to a method for preparing a gas mix for enabling respiratory stability. The method of Claim 8 comprises the steps of providing a substantially low concentration of carbon dioxide, and combining pressurized air with the carbon dioxide to form a gas mix having stabilizing effects on breathing, the pressurized air enabling the carbon dioxide at low concentrations in the gas mix to have stabilizing effects on target respiratory systems (*see page 11, lines 10-13; page 11, line 22-page 12 line 3*).

With respect to the step of providing a substantially low concentration of carbon dioxide, this step can be accomplished in a number of ways including but not limited to the use of various valves to control carbon dioxide flow (*see e.g. page 4, lines 3-5; page 3, line 29-page 4, line 2*) in combination with a gas mixing module (*see page 13, line 19-page 14, line 2*). The step of providing can also be accomplished using controlled rebreathing of carbon dioxide (*see page 9, line 25-page 10 line 5*). Substantially low concentration of carbon dioxide includes but is not limited to concentrations of less then 2% and preferably concentrations in the range of about .5% to about 1.25% (*see page 11, lines 10-13; page 11, line 22-page 12 line 3*).

With respect to the step of combining pressurized air with the carbon dioxide, this step can be accomplished in a number of ways including but not limited to use of a gas mixing module (*see page 13, line 19-page 14, line 2*).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. 35 U.S.C. § 102-First Rejection

Claims 1, 2, 6 and 7 were rejected under 35 U.S.C. § 102(b) as being anticipated by Raemer (U.S. Patent No. 5,320,093).

B. 35 U.S.C. § 103-Second Rejection

Claims 4, 5, 8, 9, 11, 12 and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raemer (U.S. Patent No. 5,320,093).

C. 35 U.S.C. § 103-Third Rejection

Claims 3 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raemer (U.S. Patent No. 5,320,093) in view of Pauley (U.S. Patent No. 5,975,078).

VII. ARGUMENT

A. Grouping of the Claims

The claims do not stand and fall together. Claims 1-13 stand as separately patentable claims.

B. Claims 1, 2, 6 and 7 are patentable under 35 U.S.C. § 102 as being unanticipated by Raemer (U.S. Patent No. 5,320,093).

Claims 1, 2, 6 and 7 were rejected under 35 U.S.C. § 102(b) as being anticipated by Raemer (U.S. Patent No. 5,320,093). The Appellant respectfully submits that claims 1, 2, 6 and 7 are not prima facie anticipated by Raemer.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 202

USPTO 202 (Fed Cir. 1983). Disclosure of each claimed element in isolation is insufficient. Anticipation further requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik Gmbh v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Still further, anticipation requires that the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ 2d. 1241 (Fed Cir. 1986).

With respect to Claims 1, 2, 6 and 7, nowhere does the disclosure of Raemer mention pressurized air. Rather, the Appellant would point out that the anesthesia gas ("fresh gas") of Raemer is not the same as the pressurized air of the present invention. Air is "a colorless, odorless, tasteless, gaseous mixture, mainly nitrogen (approximately 78 percent) and oxygen (approximately 21 percent) with lesser amounts of argon, carbon dioxide, hydrogen, neon, helium, and other gases" (*The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004). "Air" as commonly known and as used in the art is sourced directly from the atmosphere of the Earth and is inexpensive to collect and pressurize. By contrast, anesthesia gas is typically pure oxygen mixed with one or more of nitrous oxide, sevoflurane, desflurane, isoflurane, halothane, or some other gaseous anesthetic agent. Raemer specifically mentions the oxygen–nitrous oxide mixture (column 4, lines 58-60). To show that Appellant's Claim 1 reads on the cited reference, one would have to use an overly broad interpretation of "air" to mean "any gas mixture," or must creatively interpret the anesthesia gas of Raemer as using air as an anesthesia gas. The Appellant respectfully submits that the

latter case is clearly not applicable to the present invention because any anesthesia machine utilizing air as its anesthesia gas would not function as intended—and in any case would not be the "standard anesthesia machine" recited by Raemer (column 4, line 57). As to the former case, the Appellant can only aver that "air" as used in the claims is to be interpreted under its common meaning, and, identically, the meaning that would be construed by those skilled in the art: "atmospheric air or a gas composition substantially similar thereto," and not under a broader metaphorical meaning such as "any gas composition."

The Appellant would also point out that Raemer does not teach or suggest use of substantially low concentrations of CO_2, nor does Raemer teach or suggest the combination of pressurized air with CO_2 to form a gas mix for effecting respiratory stability subject. Moreover, the concentration of CO_2 delivered to the patient is not measured in the invention of Raemer. In his final rejection dated October 16, 2009, the examiner asserted that "Raemer does disclose measuring concentration of CO_2 in a gas mix delivered to the patient (see col. 5 lines 5-15)." However, and on the contrary, nowhere does the disclosure of Raemer teach or suggest measuring the concentration of CO_2 in a gas mix <u>delivered to the patient</u>. In particular, the passage cited by the examiner in his final rejection only suggests "a negative feedback control system and method which utilizes the partial pressure of the end tidal CO_2 expired by a patient to control the quantity of CO_2 which is delivered to the inspiration line 12 of breathing circuit 10." Thus, Raemer discloses only measurement of expired/exhaled CO_2, and does not suggest measuring concentration of CO_2 in a gas mix delivered to the patient. Further, examination of the closed-loop feedback control of the invention of Raemer shows it to

be incapable of measurement of the concentration of CO_2 in a gas mix delivered to the patient. Specifically, with reference to Raemer's FIG. 1, the CO_2 add controller 52 governs the addition of CO_2 to the gas mix delivered to the patient by operating a pair of time-controlled valves 37 which permit CO_2 to mix with the anesthesia gas in mixing zone 32 (see column 5, lines 15-27). If Raemer were to measure the concentration of CO_2 in this gas mix delivered to the patient, the measurement would need to take place either within this mixing zone, or at some part of the circuit downflow of the mixing zone before being introduced to the patient. However, as Raemer discloses, the only sensor therein is a flow meter placed in the mixing zone (FIG. 1 and column 7, lines 37-53). While this sensor is a safety measure intended to ensure that the patient is not receiving solely CO_2, it does not and cannot do so by measuring the CO_2 concentration in the mixing zone. This sensor is intended only to check that the flow of anesthetic gas does not fall to an unsafe level. Among sensor modalities mentioned by Raemer for this purpose are a "self-heated thermistor flow meter with an accuracy of about ±20%", "thermal transport, momentum (vane), vortex precession, or Poiseuille's law". None of these modalities is inherently capable of measuring CO_2 concentration, or even determining it by computing flow volumes.

B1. Claim 2 is patentable under 35 U.S.C. § 102 as being unanticipated by Raemer (U.S. Patent No. 5,320,093).

With regard to claim 2, Raemer does not teach a positive airway pressure (PAP) module; rather, Raemer teaches a conventional ventilator with a bellows, and in any case, the ventilator of Raemer is not providing pressurized air but is instead driving the

mechanical ventilation of anesthetic gas to an anesthetized patient. A ventilator differs greatly from a PAP in both construction and function, and a person skilled in the art could readily distinguish them. The ventilator 22 of Raemer is not even disclosed as being a component of an anesthesia machine 28, which, in Raemer, is the source of the anesthetic gas (which, as already mentioned, is different from air). Thus in Raemer, the ventilator cannot be for providing the pressurized air—rather, it aids in the circulation of the anesthetic gas (and expired gas).

B2. Claims 6 and 7 are patentable under 35 U.S.C. § 102 as being unanticipated by Raemer (U.S. Patent No. 5,320,093).

Claims 6 and 7 depend from claim 1 and inherit its patentable distinction over the cited publication.

C. Claims 4, 5, 8, 9, 11, 12 and 13 are patentable under 35 USC §103 over Raemer (U.S. Patent No. 5,320,093).

Claims 4, 5, 8, 9, 11, 12 and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raemer (U.S. Patent No. 5,320,093).

1. Standard of Review:

> To reach a proper conclusion under 35 USC §103, the decision maker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In the light of all the evidence, the decision maker must then determine whether...the claimed invention as a whole would have been obvious at that time to that person. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts.

Panduit Corp. v. Dennison Mfg. Co., 810 F2d 1561, 1566, 1 USPQ2d 1593, 1595 96 (Fed. Cir. 1987).

2. Prima facie Obviousness

A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Rickaert,* 9 F.3d 1531; 28 U.S.P.Q.2d (BNA) 1955 (Fed. Cir. 1993). The Patent and Trademark examiner bears the initial burden of presenting a prima facie case of obviousness, only shifting to the applicant if the burden is met. The Appellant respectfully submits that the Examiner has not made a prima facie case of obviousness with respect to Claims 4, 5, 8, 9, 11, 12 and 13. The Appellant incorporates its above remarks with respect to Raemer.

C1. Claims 8, 9 and 13 are patentable under 35 USC §103 over Raemer (U.S. Patent No. 5,320,093).

With regard to claims 8, 9, and 13, as submitted in the above remarks drawn to the rejections under 35 U.S.C. § 102(b), Raemer does not disclose a method for providing substantially low concentration of carbon dioxide; it is impossible to determine the concentration of carbon dioxide provided by the invention of Raemer as Raemer does not offer a method for measuring the concentration of carbon dioxide in the gas mix provided to the patient. Further, Raemer does not teach or suggest that its gas mix may have stabilizing effects on target respiratory systems as claimed, but rather, is aimed at restoring ventilatory drive (i.e., the balance between hyperventilation and hypoventilation following the cessation of self-governed breathing during anesthesia). With regard to

claim 9, Appellant would incorporate the above remarks concerning the distinction between a PAP and a ventilator: the ventilator disclosed by Raemer is not the substantial equivalent of a PAP either in construction or in function in the present case.

C2. Claims 4, 5, 11 and 12 are patentable under 35 USC §103 over Raemer (U.S. Patent No. 5,320,093).

With regard to claims 4, 5, 11 and 12, which claim specific concentrations of CO_2 in the gas mix supplied to the patient, the Appellant would further point out that the examiner admitted in his final office action dated October 16, 2009 that Raemer does not quantitatively disclose concentrations of carbon dioxide in the gas mix. Specifically, the examiner stated that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Raemer's invention by providing carbon dioxide in the gas mix that is less than 2% in order to provide the cleanest gas possible, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." The Appellant respectfully submits that the examiner's "official notice" assertion does not make sense, is further untrue, and that the examiner provides no evidence to support this assertion.

The assertion does not make sense because if the intent of the claimed invention were to "provide the cleanest gas possible," as alleged by the examiner in his final office action, carbon dioxide would be omitted from the gas mix altogether, as carbon dioxide is a waste product of respiration and is not required by the body under conditions of normal respiratory stability. The intent of the invention is not to "provide the cleanest gas

possible," but rather to provide carbon dioxide in substantially low concentrations so as to provide a therapeutic effect on respiratory stability. As stated in the specification at page 11, lines 25-26, "[p]rior to Applicants' discovery of such, use of CO_2 was not considered effective in doses below a concentration of 2%."

Further, the "official notice" assertion is untrue because, as averred in the specification at page 11, lines 10-17, "the stabilizing properties [of CO_2] at low doses (less than 2%) when given in conjunction with PAP as discovered by Applicants are heretofore not well documented or known. No equipment is currently available to deliver CO_2 and pressurized air in precisely metered combinations, either in a clinical or home setting. Precise metering of these gases is essential for therapeutic use since both gases, and especially CO_2, have the potential for adverse side effects if an overdose is given. Metering must be maintained over a range of demand conditions." Thus, use of this precise metering is not of "routine skill in the art" and the invention claimed was not a discovery of "optimum or workable ranges."

The Appellant would further point out that the examiner also failed to introduce factual evidence supporting this "official notice" assertion. The MPEP requires an examiner to "provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge [or what is 'routine skill in the art' as alleged by the examiner]." See MPEP § 2144.03 B. The MPEP also requires an examiner to "'point to some concrete evidence in the record in support of these findings' to satisfy the substantial evidence test. If the examiner is relying on personal knowledge to support the finding of what is known in the art, the

examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding." See MPEP § 2144.03 C.

Accordingly, the Appellant respectfully suggests that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the examiner. As such, the Appellant submits that the examiner should have submitted an affidavit detailing the personal knowledge upon which his rejection was based. See 37 C.F.R. § 1.104(d)(2) as previously requested by the Appellants.

D. Claims 3 and 10 are patentable under 35 USC §103 over Raemer (U.S. Patent No. 5,320,093) in view of Pauley (U.S. Patent No. 5,975,078).

Claims 3 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raemer (U.S. Patent No. 5,320,093) in view of Pauley (U.S. Patent No. 5,975,078). The Appellant submits the claims are not prima facie obvious in light of these rejections.

1. Standard of Review:

> To reach a proper conclusion under 35 USC §103, the decision maker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In the light of all the evidence, the decision maker must then determine whether...the claimed invention as a whole would have been obvious at that time to that person. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts.

Panduit Corp. v. Dennison Mfg. Co., 810 F2d 1561, 1566, 1 USPQ2d 1593, 1595 96 (Fed. Cir. 1987).

2. Prima facie Obviousness

A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Rickaert*, 9 F.3d 1531; 28 U.S.P.Q.2d (BNA) 1955 (Fed. Cir. 1993). The Patent and Trademark examiner bears the initial burden of presenting a prima facie case of obviousness, only shifting to the applicant if the burden is met. The Appellants respectfully submit that the Examiner has not made a prima facie case of obviousness with respect to claims 3 and 10.

With respect to claims 3 and 10, the Appellant incorporates its above remarks regarding Raemer. With respect to claims 3 and 10, the Appellant would also point out that neither Raemer nor Pauley, alone or in combination, mention therapeutic use of substantially low concentrations of CO_2 or the combination of substantially low concentrations of CO_2 and pressurized air to form a respiratory stabilizing gas mix as recited in claims 1 and 8 upon which claims 3 and 10 depend. The Appellant further notes that with regard to claim 3, the disclosure of Pauley does not teach an apparatus that provides a PCVSM that includes an incubator, a tent, a facemask, and a nasal cannula, as alleged by the examiner. Rather, Pauley discloses only a facemask.

D1. Combination of the teachings.

The Examiner has not given the Appellant any reason, suggestion, or motivation in the references, from the references cited as a whole, or evidence external to the references, for a person of ordinary skill to have combined or modified the references. "When a rejection depends on a combination of prior art references, there must be some

teaching, suggestion, or motivation to combine the references." *In re Rouffet, 149* F.3d 1350, 1355, 47 U.S.P.Q.2d (BNA) 1453 (Fed. Cir. 1998). Furthermore, "rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA)1554 (Fed. Cir. 1996). Therefore in order to prevent the use of hindsight based on the invention the Examiner must show reasons that the skilled artisan, confronted with the same problem as the inventor and with no known knowledge of the claimed invention, would select the elements from the cited prior art references for combination. *In re Rouffet,* 149 F.3d 1350, 1355, 47 U.S.P.Q.2d (BNA) 1453 (Fed. Cir. 1998).

The court further has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. *In re Rouffet,* 149 F.3d 1350, 1357, 47 U.S.P.Q.2d (BNA) 1453 (Fed. Cir. 1998). The Supreme Court recently reaffirmed this approach and recognized that a reason to combine references may be contained in interrelated teachings of multiple patents, market or design demands, or the background knowledge of a person having ordinary skill in the art. *KSR Int'l Co. v. Teleflex, Inc.* No. 04-1350 at 14 (U.S. Apr.30, 2007).

E. Conclusion

For at least the reasons given above, Appellant respectfully submits that the Examiner has failed to make a prima facie case of both anticipation and obviousness. Accordingly, Appellant and respectfully requests that the Board reverse the Examiner's rejections and find Claims 1-13 allowable.

If there are any other fees due in connection with the filing of this Brief on Appeal, please charge these fees to Deposit Account No. 502704. If a fee is required for an extension of time under 27 C.F.R. §1.136 not accounted for above, such extension is requested and the fee should also be charged to the above-mentioned Deposit Account.

Respectfully submitted,

3/12/09
Dated

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VIII. CLAIMS APPENDIX

1. (Previously Presented) A device for stabilizing breathing comprising

a source of carbon dioxide;

an assembly for combining pressurized air with substantially low concentrations of the carbon dioxide resulting in a gas mix;

a patient centric ventilatory space module (PCVSM) coupled to the assembly providing the resulting gas mix for inhalation by a given target, said inhalation of the gas mix effecting respiratory stability of said target.

2. (Original) A device as claimed in Claim 1 wherein the assembly includes a positive airway pressure module for providing the pressurized air.

3. (Original) A device as claimed in Claim 1 wherein the PCVSM includes any of: an incubator, a tent, a facemask, and a nasal cannula.

4. (Original) A device as claimed in Claim 1 wherein concentration of carbon dioxide in the gas mix is less than 2%.

5. (Original) A device as claimed in Claim 1 wherein concentration of carbon dioxide in the gas mix is between about .5% and about 1.25%.

6. (Original) A device as claimed in Claim 1 wherein at least one of the source, the assembly and the PCVSM is computer processor controlled to modulate concentration of carbon dioxide in the gas mix.

7. (Original) A device as claimed in Claim 6 wherein the computer processor modulates concentration of C02 in the gas mix as a function of any combination of sensed concentration of carbon dioxide in the PCVSM, sensed target state and detected system changes.

8. (Original) A method for preparing a gas mix for enabling respiratory stability, comprising the steps of:

providing a substantially low concentration of carbon dioxide; and

combining pressurized air with the carbon dioxide to form a gas mix having stabilizing effects on breathing, the pressurized air enabling the carbon dioxide at low concentrations in the gas mix to have stabilizing effects on target respiratory systems.

9. (Original) The method of Claim 8 wherein the step of combining includes employing positive airway pressure.

10. (Original) The method of Claim 8 wherein the step of combining includes utilizing a face mask worn by a target patient.

11. (Original) The method of Claim 8 wherein the step of providing includes employing carbon dioxide at concentrations of less than 2%.

12. (Original) The method of Claim 8 wherein the step of providing includes employing carbon dioxide at concentrations in the range of about .5% and about 1.25%.

13. (Original) The gas mix formed by the process of Claim 8.

14. (Withdrawn) A gas modulation system comprising:

a source of a first gas;

means for mixing the first gas into a gas mix for use in a patient centric ventilatory space module (PCVSM);

a sensor, located substantially at the PCVSM, which measures concentration of the first gas in the PCVSM; and

a control processor which, based on a signal from the sensor, controls concentration of the first gas in the gas mix.

15. (Withdrawn) The gas modulation system of Claim 14 wherein the PCVSM is any one of an incubator, a tent, a facemask, and a nasal cannula.

16. (Withdrawn) The gas modulation system of Claim 14 wherein the PCVSM is substantially leak-proof.

17. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the first gas is C02.

18. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein pressurized air is a second gas in the gas mix.

19. (Withdrawn) The gas modulation system as claimed in Claim 18 further comprising a positive airway pressure (PAP) module which provides the pressurized air.

20. (Withdrawn) The gas modulation system as claimed in Claim 18 wherein C02 in the gas mix is at a substantially low concentration.

21. (Withdrawn) The gas modulation system as claimed in Claim 20 wherein C02 is at a concentration below 2%.

22. (Withdrawn) The gas modulation system as claimed in Claim 20 wherein C02 is at a concentration in a range of about .5% to about 1.25%.

23. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor determines, from a signal from the sensor, concentration of C02 in a patient's end tidal breath.

24. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor controls concentration of C02 for a patient diagnosed as having sleep disordered breathing (SDB).

25. (Withdrawn) The gas modulation system as claimed in Claim 24 wherein the patient has further been diagnosed as having Cheyne-Stokes respiration.

26. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor controls concentration of C02 for a patient diagnosed as having an "Apparent Life Threatening Experience" (ALTE).

27. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor controls concentration of C02 for a patient being diagnosed as having apnea of prematurity.

28. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the source of the first gas is a pressurized source; and

the gas modulation system further comprises a control value module which regulates flow of the first gas from the pressurized source to the mixing means, the control valve module responding to a control signal from the control processor.

29. (Withdrawn) The gas modulation system as claimed in Claim 28, the control valve module comprising a solenoid valve.

30. (Withdrawn) The gas modulation system as claimed in Claim 28, the control valve module comprising a proportional valve.

31. (Withdrawn) The gas modulation system as claimed in Claim 28 further comprising a limiting orifice placed in series with the control valve module.

32. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the mixing means is one of (a) a gas mixing module having an input plenum, an output plenum and a flow channel which connects the input plenum to the output plenum; and (b) a tube or other enclosure without an input or output plenum.

33. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising any combination of:

(a) a flow meter which provides a visual or electrical indication of flow of the first gas into the mixing means; and

(b) an input flow sensor which measures flow of the first gas into the mixing means, the input flow sensor providing a signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal;

(c) a flow meter which provides a visual or electrical indication of flow of bleed air vented from the PCVSM; and

(d) a PCVSM exhaust air bleed sensor which measures flow of PCVSM exhaust bleed air, the PCVSM bleed air sensor providing a signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal.

34. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising:

a proportional valve which, responsive to a control signal from the control processor, regulates flow of bleed air vented from the PCVSM, the control processor dynamically controlling the proportional valve in response to detected system changes.

35. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising:

a manually operated valve which regulates flow of bleed air vented from the PCVSM.

36. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the control processor controls concentration of the first gas in the gas mix responsive to patient state information from any combination of: thermistors, strain gauges, skin conductance monitors, arterial contraction monitors, transcutaneous blood gas monitors and physiological signals.

37. (Withdrawn) The gas modulation system as claimed in Claim 36, wherein physiological signals include any of EEG signals, EKG signals, respiratory data or end tidal carbon dioxide signals.

38. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising:

a pneumatachograph mounted in proximity to the PCVSM, the pneumotachograph measuring inspired and expired breath volume and providing a pressure signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal.

39. (Withdrawn) The gas modulation system as claimed in Claim 14, further comprising:

a display monitor, connected to the control processor, the control processor displaying on the display monitor a scrolling chart recorder which displays at least one of:

C02 concentration, 02 concentration, control processor control state, a sensor signal, and a physiological signal.

40. (Withdrawn) The gas modulation system as claimed in Claim 14, further comprising:

a remote interface to the control processor such that the control processor is controllable remotely from a remote workstation.

41. (Withdrawn) The gas modulation system as claimed in Claim 40, wherein the remote interface is a wired or wireless TCP/IP connection.

42. (Withdrawn) The gas modulation system as claimed in Claim 14, further comprising:

a gas sampling sensor which monitors concentration of at least the first gas within the mixing means, the gas sampling sensor providing a signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal.

43. (Withdrawn) The gas modulation system as claimed in Claim 42, wherein the gas sampling sensor monitors concentrations of carbon dioxide (C02) and oxygen (02).

44. (Withdrawn) The gas modulation system as claimed in Claim 14, wherein the control processor continuously receives and analyzes incoming data and indicates an alarm condition based on the incoming data and at least one of the following parameters:

maximum first gas flow;
maximum inspired first gas;
maximum arterial C02;
maximum end tidal carbon dioxide; and
maximum percent first gas in the mixing means,

the control processor stopping or reducing delivery of the first gas when an alarm condition is present.

45. (Withdrawn) The gas modulation system as claimed in Claim 44, the control processor sounding an audible alarm when an alarm condition is present.

46. (Withdrawn) The gas modulation system as claimed in Claim 14, wherein said system is adapted for use in a non-clinical setting, including any of:

(a) the source of the first gas being a canister having an orifice of size which limits maximum flow according to a specified limit;

(b) the system further comprising recording and reporting means;

(c) the recording and reporting means being remotely accessible; and

(d) the recording and reporting means being accessible via a dial-up connection.

47. (Withdrawn) A carbon dioxide (C02) based system for enabling respiratory stability, comprising:

a substantially leak-proof mask having an exhaust vent, said mask for use by a user;

a positive air pressure (PAP) module which delivers pressurized air to the mask;

a deadspace reservoir attached to the mask and retaining C02 expired by the user for subsequent re-inhalation by the user;

a sensor, located substantially at the mask, which measures concentration of carbon dioxide in the mask, said concentration dynamically changing as a function of the user's breathing; and

a control processor coupled to receive signals from the sensor, the control processor, based on the signals from the sensor, controlling the exhaust vent of the mask to control the level of carbon dioxide in the mask, such that levels of carbon dioxide for effecting respiratory stability are maintained in the mask and inhaled by the user.

48. (Withdrawn) The carbon dioxide based system of Claim 47, wherein the deadspace reservoir is formed by a length of hose.

49. (Withdrawn) The carbon dioxide based system of Claim 47, wherein the deadspace reservoir holds approximately 500 ml. of gas.

50. (Withdrawn) The carbon dioxide based system of Claim 47, wherein the exhaust vent includes one of: a proportional valve controllable by the central processor, a user controllable needle valve, and a variable orifice.

51. (Withdrawn) The carbon dioxide based system of Claim 47 wherein levels of below about 2% C02 are maintained in the mask.

52. (Withdrawn) The carbon dioxide based system of Claim'47 wherein levels of between about .5% and 1.25% of C02 are maintained in the mask.

53. (Withdrawn) A method for regulating carbon dioxide (C02) about a patient, comprising:

providing a substantially leak-proof mask having (i) an exhaust vent and (ii) a deadspace reservoir for retaining a patient's expired C02 for subsequent re-inhalation by the patient, said mask being worn by the patient;

supplying pressurized air to the mask;

using computer means, measuring concentration of carbon dioxide in the mask, said concentration dynamically changing as a function of the patient's breathing; and

based on measured concentration, controlling the concentration of carbon dioxide in the mask, and hence the concentration of C02 inhaled by the patient.

54. (Withdrawn) The method of Claim 53, wherein the deadspace reservoir comprises a length of hose.

55. (Withdrawn) The method of Claim 53, wherein the deadspace reservoir holds approximately 500 ml. of gas.

56. (Withdrawn) The method of Claim 53, wherein the step of controlling includes using one of a proportional valve, a needle valve and a variable orifice in the exhaust vent.

57. (Withdrawn) The method of Claim 53 wherein the step of controlling includes maintaining concentration of carbon dioxide at a level just sufficient for effecting respiratory stability.

58. (Withdrawn) A method as claimed in Claim 57 wherein concentration of carbon dioxide is maintained below about 2%.

59. (Withdrawn) A method as claimed in Claim 57 wherein concentration of carbon dioxide is maintained between about .5% and about 1.25%.

60. (Withdrawn) A computer program product for regulating concentration of a first gas in a gas mix used in a patient centric ventilatory space module (PCVSM), the computer program product comprising a computer usable medium having computer readable code thereon, including program code which:

receives flow information of the first gas;

receives sampled concentration of at least the first gas in the gas mix;

receives concentration data of at least the first gas in a patient's inhaled and expired breath, said concentration data being measured substantially at the PCVSM; and

analyzes the flow of the first gas, gas mix concentration of the first gas and concentration of the first gas in a patient's inhaled and expired breath, and based on said analysis regulates concentration of the first gas in the gas mix.

61. (Withdrawn) A method of treating respiratory instability in a patient, comprising the steps of:

mixing effectively minimum concentrations of C02 with pressurized air to form a gas mix; and

delivering the gas mix to a patient to inhale.

62. (Withdrawn) The method as claimed in Claim 6 1 wherein the step of mixing employs about 2% C02.

63. (Withdrawn) The method as claimed in Claim 61 wherein the step of mixing employs between about .5% and 1.25% C02.

64. (Withdrawn) The method as claimed in Claim 61 wherein the step of mixing employs positive airway pressure.

65. (Withdrawn) The method as claimed in Claim 61 wherein the step of delivering includes temporarily ceasing delivery of the gas mix during periods of detected stable breathing by the patient.

66. (Withdrawn) The method as claimed in Claim 61 wherein the step of delivering is performed during times of detection of the patient being at a point in a breathing cycle where expired C02 levels are decreasing.

67. (Withdrawn) The method as claimed in Claim 66 wherein the step of delivering includes delivering over a relatively short period of time with respect to the breathing cycle.

68. (Withdrawn) The method as claimed in Claim 61 wherein the step of mixing is performed in a deadspace area of a mask worn by the patient, and source of C02 is the patient's expired breath; and

further comprising the step of venting the mask to control concentration of the C02.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

No related appeal or interference.